ergodesk duo

Desktop Unit for Measurement of Blood Pressure and Oxygen Saturation

User Manual

erg 2010000123000 • Version 06/2010 • English

Manual

This manual was written with the utmost care. Should you still find details that do not correspond with the system, please let us know and we will correct the issue as soon as possible.

We reserve the right to modify the design and technical features of the device and are not bound by the information and illustrations provided in this manual.

All trademarks appearing in this document are trademarks of their respective owners. Their protection is acknowledged.

No part of this manual may be reprinted, translated or reproduced without the manufacturer's written permission.

This manual is not subject to any change order service. Please contact the manufacturer for the latest document
revision.

ergoline GmbH
Lindenstraße 5
72475 Bitz
Germany

Tel.: +49-(0) 7431 98 94 - 0
Fax: +49-(0) 7431 98 94 - 128
e-mail: info@ergoline.com
http: www.ergoline.com
Printed in Germany

CE 0123

CONTENTS

Declaration of Conformity 7

General Information 9

Intended Use 10

Safety Information 11

Functional Principle 13
- Oscillometric Blood Pressure Measurement 13
- Oxygen Saturation Measurement (SpO2) 13

Accuracy, Notes, Problems 14
- Oscillometric Blood Pressure Measurement 14
- Oxygen Saturation Measurement 15

Start-up and Initial Preparation 16
- Unpacking, Inspection upon Delivery 16
- Power Supply 17
- Connecting the SpO2 Sensor 17
- Connecting the Blood Pressure Cuff 17

GDT Interface Installation 18
- Software Installation 18
- GDT Settings 19
- GDT Communication Routine 20

Controls and Indicators 21
- Keyboard 21
- LCD Screen 21

Operation 22
- Starting a Measurement 22
- Setup Menu 23

Blood Pressure Cuffs 24
- Cuff Application 24
- SpO2 Sensors 25

Cleaning and Maintenance **26**
Equipment Surface 26
Cuff Cleaning and Disinfection 26
Sensor Cleaning and Disinfection 27
Maintenance, Technical Inspection of the Measuring System (MTK) 27
Calibration Mode for BP Measurement System 28
SpO2 Calibration 28

Disposal of the Product **29**

Technical Specifications **30**

Electromagnetic Compatibility EN 60601-1-2 **31**

ergoline

Konformitätserklärung
Declaration of conformity

Gemäß EG-Richtlinie 93/42/EWG vom Juni 1993
Acc. MDD 93/42/EEC. June 1993

Wir
We

ergoline GmbH
Lindenstraße 5
D-72475 Bitz

erklären in alleiniger Verantwortung, daß das
declare our sole responsibility that the

Produkt: ergodesk duo
Product: ergodesk duo

auf das sich diese Erklärung bezieht, mit der folgenden Norm oder normativem Dokument übereinstimmt:
to which this declaration relates is in conformity with the following standard or other normative document:

EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang I
MDD 93/42/EEC I

Die Medizinprodukte werden von der „Benannten Stelle" TÜV überprüft und tragen zum CE Kennzeichen die vierstellige
The medical products will be checked by the „Notified Body" TÜV and are marked with the CE Symbol and the four-digits

No. 0123

nach
accordings as

EG-Richtlinie für Medizinprodukte 93/42/EWG Anhang II / 3
MDD 93/42/EEC II / 3

Ort/City:

Bitz, 11.07.2007

Beginn der Gültigkeit / Begin of the validity:
Datum/Date: 11.07.2007

Axel Bodmer

General Information

- The product ergodesk duo bears the CE marking CE-0123 indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices and fulfills the essential requirements of Annex I of this directive. It has an internal power source and is an MDD class IIb device.

- The device fulfills the requirements of standard EN 60601-1 "Medical Electrical Equipment, Part 1: General Requirements for Safety"as well as the electromagnetic immunity requirements of standard EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Devices".
  The radio-interference emitted by this product is within the limits specified in CISPR11/ EN 55011, class B.

- The symbol means:

  Refer to User Manual.
  It indicates points which are of particular importance in the operation of the device.

- This manual is an integral part of the equipment. It should be available to the equipment operator at all times.

- Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and user safety.

- Please note that information pertinent to several chapters is given only once. Therefore, carefully read the entire manual.
  (cf. German Medical Devices Operator Ordinance, §9, section 1, and §2, section 5).

- This manual reflects the equipment specifications and applicable safety standards valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.

- The ergoline quality management system complies with the standards EN ISO 9001 and EN ISO 13485.

- The safety information given in this manual is classified as follows:

Danger

indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning

indicates a hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

Caution

indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/ property damage.

- To ensure maximum patient safety and interference-free operation and to maintain the specified measuring accuracy, we recommend using only original accessories approved by ergoline GmbH.

- The warranty does not cover damage resulting from the use of unsuitable accessories and consumables from other manufacturers.

- ergoline is responsible for the safety, reliability, and performance of the equipment, only if:
  - assembly operations, extensions, readjustments, modifications, or repairs are carried out by ergoline GmbH or by persons authorized by ergoline and
  - the equipment is used in accordance with the instructions given in this manual.

ergoline GmbH
Lindenstrasse 5
72475 Bitz
Germany

Phone: +49-(0)-7431 - 9894 -0
Fax: +49-(0)-7431 - 9894 -128
e-mail: info@ergoline.com
http: www.ergoline.com / www.ergoline.eu

Intended Use

ergodesk duo is a sphygmomanometer for the non-invasive measurement of the blood pressure as well as for determining the functional oxygen saturation (SpO2) in human, arterial blood and for measuring the pulse rate.

With the appropriate blood pressure cuffs and SpO2 sensors, it can be used on adults, children and babies.

ergodesk duo is not suitable for use with neonates or in intensive-care medicine.

Biocompatibility

The parts of the product described in this manual, including all accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards if applied as intended.
If you have questions in this matter, please contact ergoline or a representative.

Applicable Laws, Regulations and Directives

- 93/42/EEC (Medical Device Directive of the EU)
- 89/336/EEC (Electromagnetic Compatibility Directive of the EU)
- EN 1060-1 Non-invasive sphygmomanometers, Part 1: General requirements
- EN 1060-3 Non-invasive sphygmomanometers, Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

Safety Information

Danger

• Explosion Hazard •

The device is not designed for use in areas where an explosion hazard may occur.
Explosion hazards may result from the use of flammable anesthetics, skin cleansing agents or disinfectants.

Caution

• Patient Hazard, Equipment Damage •

Devices may be connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the user, or the environment as a result.

In those instances where there is any element of doubt concerning the safety of connected equipment, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the user, or the environment as a result of the proposed combination of equipment. Compliance with the standard IEC 60601-1-1 must always be ensured.

ergodesk duo can be connected to and operated in conjuction with a PC where the ergodesk duo GDT driver is installed.

Caution

• Patient Hazard, Equipment Damage •

Before using the equipment, the operator must ascertain that it is in correct working order and operating condition.

If the accuracy of any reading is questionable, first check the patient's vital signs by alternate means. Then check the device for proper functioning.

The user must be trained in the use of the device.

Only persons who are trained in the use of medical technical equipment and are capable of applying it properly are authorized to apply such equipment.

There are no user-replaceable components inside the device. Do not open the housing (notify Service).

Warning

• Patient Hazard, Equipment Damage •

Do not use defective equipment. Replace all parts that are broken, worn or contaminated.

ergodesk duo is not intended for use as a vital signs physiological monitor and has no adjustable alarm limits.

The device is not designed for use in areas where there is any danger of explosion.

ergodesk duo and all accessories must only be employed by persons with the requisite expertise. ergodesk duo is packed in an appropriate container for shipment. Do not use ergodesk duo or the corresponding sensors if any of the parts exhibit signs of damage from transport or other causes.

ergodesk duo is not suitable for operation in the vicinity of MRI devices or X-ray equipment and must not be operated in such an environment.

Exceeding the operation parameters or failure to observe the measurement conditions causes incorrect readings and, at worst, damage to the equipment.

Applying the sensor improperly or at inappropriate sites leads to incorrect measurement results, the sensor cable may tie off parts of the body, the finger clip may shear off the skin, etc.

Do not use sensors or accessories other than those offered for this device. The sensors and cables must be in perfect condition.

Using third-party items may cause equipment failure and loss of biocompatibility.

Measurements performed on persons taking substances that change the color of the blood or receiving intravascular dyes (e.g. methylene blue or indocyanine green) or exhibiting high levels of dysfunctional hemoglobin (e.g., carbon monoxide poisoning) may be extremely inaccurate.

The device is intended to assist in establishing a diagnosis. For diagnosing the patient's condition, ergodesk duo must always be interpreted in context with other clinical signs and symptoms. A clinical assessment on the basis of ergodesk duo alone is not permitted.

Functional Principle

Oscillometric Blood Pressure Measurement

The oscillometric measuring method is based on oscillations caused by pulsations of the brachial artery that is compressed by an inflated arm cuff. In the cuff, these pulsations cause rapid, small-amplitude variations in pressure. The device is essentially an oscillometer comprising an inflatable cuff which is connected to a pneumatic system for controlled inflation and deflation of the cuff.

An integrated sensor acquires the measuring signal and passes the cuff pressure on to a conversion/amplification unit. From this data and their variation in the course of the measurement, the device calculates the systolic, the diastolic and the mean blood pressure readings and the pulse rate.

While the cuff pressure is continually released, the amplitude of the cuff pressure oscillations increases many times over. The pressure at this point in time corresponds to the systolic blood pressure. As the cuff pressure is further released, the amplitude of the oscillations increases until it reaches a maximum, after which it decreases again. The point where the amplitude drops abruptly corresponds to the diastolic pressure.

Oxygen Saturation Measurement (SpO2)

Non-invasive pulse oximetry is based on two principles. First, the color of the blood which is influenced by oxygen saturation is determined in the red and infrared ranges (spectrophotometry). Second, the amount of arterial blood in the tissue (and hence the light absorbed by the blood) varies with the pulsations caused by the heart ejecting blood into the arteries (plethysmography).

The difference in color caused by oxygen saturation is due to the optical properties of the hemoglobin molecule or, more precisely, the organic heme component. Hemoglobin is responsible for transporting oxygen in blood through oxygenation (O2Hb). Oxygen is released again, which means that the blood is deoxygenated (oxygen saturation decreases) and loses its red color. This influences the absorption of red light to a greater extent than that of infrared light.

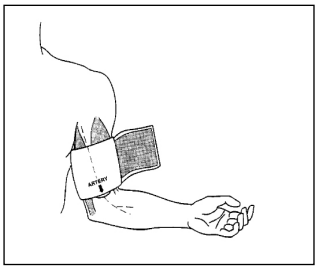
To determine the arterial oxygen saturation, the pulsation of the arterial blood flow is used. The blood volume changes during systole and diastole and this has an effect on light absorption. Since only the change in light absorption is evaluated, non-pulsating absorbing matter, such as tissue, bones and venous blood, does not affect the measurement.

The light sources for this measurement are a red and an infrared LED, and a photodiode acts as detector. The pulse oximeter measures the ratio of red to infrared pulsating absorption, which is directly proportional to the oxygen saturation and, furthermore, indicates oxygen saturation. In addition, the time interval between pulsations is converted to the pulse rate and also displayed.

Accuracy, Notes, Problems

Oscillometric Blood Pressure Measurement

Make sure that the cuff is at the same level as the heart to obtain accurate blood pressure measurements.
If this is not ensured, the hydrostatic pressure of the liquid column in the blood vessels will falsify the measurement results. When the patient is sitting, standing or supine (lying on his back) during measurements, the cuff is automatically at the correct level.



Note

- *Verify circulation of the blood in limbs used for frequent measurements.*
- *Be aware that SpO2 measurements will be affected by blood pressure measurements performed on the same arm.*
- *During a measurement, the cuff must be level with the heart. When the cuff is at a higher level, you must add approx. 0.75 mmHg to the result for each cm, or deduct that much for each cm the cuff is below the heart.*
- *Avoid kinks in the tubing during measurements and do not knock against the tubing. The patient's arm should not move while a measurement is in progress.*

Warning

Use only the cuffs listed in this manual. These cuffs ensure patient safety and equipment protection. Liquids must not be allowed to enter the cuff. Apply the cuff directly on the skin. Rolled up sleeves must not impede blood circulation in the upper arm.

Note

Place the cuff snugly around the limb being used. The cuff, however, must not compress the blood vessels.
Overtight cuffs may constrict blood vessels or cause skin lesions and hematomas.

Oxygen Saturation Measurement

To be able to correctly determine the oxygen saturation and the pulse rate, the device requires a detectable pulse wave. If no pulse wave can be detected or if the pulse wave is very weak, the readings may be incorrect. Strong motion artifacts may also lead to incorrect readings. Only when the green signal quality LED blinks at the frequency of the pulse rate are the displayed measuring values within the defined accuracy range.

Note

Artifact leveling is used to suppress motion artifacts in the measurement of SpO2 and pulse rate. In addition, the pulse rate is checked for plausibility.

By reference measurements against dyshemoglobin-free blood by means of fractional saturation measurement (CO oximeter), the pulse oximetry measurement system of the device is calibrated for oxygen saturation of hemoglobin. The presence of high levels of dysfunctional hemoglobin affects the measurement accuracy. Similarly, the measurement accuracy may be degraded by intravascular dyes.

Warning

If the accuracy of any reading is questionable, first check the patient's vital signs by alternate means. Then check the device for proper functioning.

Start-up and Initial Preparation

Unpacking, Inspection upon Delivery

If the packaging exhibits any signs of damage, notify the shipping agent immediately.
Unpack ergodesk duo and the accessories. If a part is missing or damaged, contact your dealer or ergoline's service team.

Functional Test

Before using ergodesk duo, check the device for proper functioning. To do so, follow the instructions given in this section.

Parts List

1 ergodesk duo
1 Blood pressure cuff for adults
1 SpO2 finger sensor
1 User Guide
1 CD with the GDT driver software
1 AC adapter
1 USB data cable

Power Supply

Connect the supplied AC adapter to line power and to the device.

Connecting the SpO2 Sensor

Plug the SpO2 sensor cable into the corresponding socket.

Connecting the Blood Pressure Cuff

Connect the cuff coupling to the device.

GDT Interface Installation

Software Installation

Note

Install the driver software before connecting ergodesk duo to the PC.

- Insert the ergodesk GDT CD into the CD-ROM drive.
- The installation will start automatically when the auto start function of the CD ROM drive is enabled.
  Otherwise:
  - Open Windows Explorer.
  - Select the CD ROM drive.
  - Double-click on setup.exe.
- The installation routine will start.
- The USB driver is installed first (virtual COM interface), the actual ergodesk duo GDT driver is installed afterwards.
- A new symbol for the ergodesk duo driver appears automatically in the task bar (bottom right).

- Right-clicking this icon will display the GDT link setup menu or terminate the GDT driver.

Note

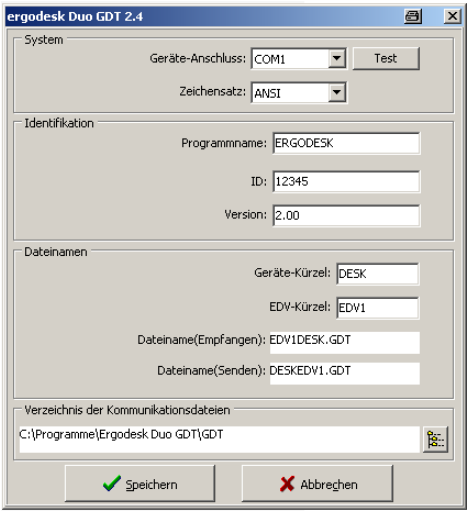
It is recommended to add the program ErgoDesk_GDT.exe *to the startup menu of the PC.*

- Connect ergodesk duo to the PC (USB cable).

GDT Settings

- Set the (virtual) COM interface to which ergodesk duo is connected.
  Press the [Test] key to check the communication link.

- All other settings must be adapted to the requirements of the electronic office or hospital management system.



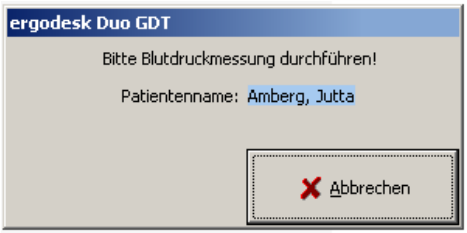
GDT Communication Routine

ergodesk duo comes with a GDT interface driver. Once the program is started on the PC, the set folder will be permanently monitored for GDT files.

If the driver detects a GDT file, the data will be sent to ergodesk duo.

The ergodesk duo display will show the corresponding patient name.

The user will then be prompted to perform the measurement.



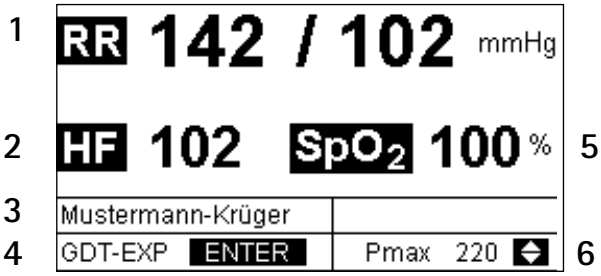
After the measurement, the [Enter] key is pressed on ergodesk duo to send the results to the PC - the GDT driver automatically generates the corresonding GDT result file.

Controls and Indicators

Keyboard

1	Stop key	terminates an active blood pressure measurement	4	UP/DOWN key	selects menu items selects inflation pressure
2	START key	starts a new blood pressure measurement	5	ENTER key	confirms settings / GDT export
3	MENU key	displays the setup menu			

LCD Screen



1	BP	systolic/diastolic pressure readings	4	SOFTKEYS	indicate the respective functions of [ENTER] etc.
2	HR	heart rate	5	SpO2	oxygen saturation value (%)
3	Name	patient name (in GDT mode only)	6	Pmax	maximum inflation pressure

Operation

Keyboard

Six keys are provided on the device. The START key starts a new blood pressure measurement. The STOP key aborts a measurement in progress.

Switching the Device ON and OFF

Connecting the device to the power supply switches it on. If the device is not used for a measurement, it will automatically switch off after the Auto Power Off time set in the menu.

Backlight

The backlighting of the display is white. The illumination is automatically activated by switching the device on.

Starting a Measurement

The <START> key on ergodesk duo starts the measurement. The device inflates the cuff to the selected P-START pressure and measures the blood pressure while the cuff is being deflated. The saturation value appears on the display as soon as the sensor is applied to the finger.

The measurement results appear on the LC display.

Note

If the P-START pressure is below the systolic blood pressure, the error message "BP out of range" will be displayed. Adapt the P-START pressure to the patient being examined.

Setup Menu

You display the setup with the [Menu] button.

An explanation of the different menu items is given below:

Memory
The most recent readings are displayed.

Setup
The menu item allows you to set the pressure in mmHg for reinflation, the Auto Power Off time, the pulse indication and the operating language.

System Reset
The device runs a complete re-start.

FW Update
Select this menu item to display the software version implemented in the device.
For software updates, please contact your dealer or ergoline's service team.

Calibration
From this menu item you access the functions to perform the necessary offset and pressure calibrations. For more information refer to the Cleaning and Maintenance section in this manual.

Blood Pressure Cuffs

ergodesk duo can be used with different sizes of cuffs (length of tubing is always 120 cm):

Standard adult:
arm circumference 24 to 32 cm
Large arms adult:
arm circumference 32 to 42 cm
Standard child:
arm circumference 17 to 26 cm

Select the appropriate cuff size (see cuff label). Undersized cuffs will yield too high a pressure, whereas oversized cuffs yield too low a pressure. Replace cuffs at regular intervals. Damaged Velcro fasteners may prevent correct BP measurements.

Cuff Application

Place the cuff on that arm of the patient which is used less frequently during normal daily activities: on adults about 2 fingers' breadth above the bend of the elbow, on children a little closer. Bending the arm must not change the cuff level.

Note

- *The side with the "Patient" label must face the skin.*
- *The arrow should be located above the brachial or femoral artery.*
- *The cuff should fit snugly around the limb, but not compress the blood vessels.*
- *Ensure that the tube is not kinked or blocked during the measurement.*

SpO2 Sensors

The SpO2 sensors are transmission sensors equipped with two LEDs with wavelengths of 660 nm and 905 nm and a photodetector for exactly this spectrum.
To ensure optimal measuring accuracy, ergodesk duo identifies the respective sensor types.

Sensor	Sensor type	Patient weight
F-3227	Finger sensor	>20 kg
FS-3227	Finger sensor, small	>20kg
ES-3227	Ear sensor	>30kg
W-3227	Wrap sensor	>1kg
R-3227	SoftTip® large	>20kg
RM-3227	SoftTip® medium	>20kg
RS-3227	SoftTip® small	>20kg

Note

- *Before using a sensor, carefully read the corresponding instructions for use with all warnings and other relevant information.*
- *Do not use damaged sensors. Do not use sensors with exposed optical components.*
- *For SpO2 measurements, use only ergoline sensors.*
- *Considerations relating to the choice of sensors include the patient's weight and degree of activity.*
  Check the patient to determine adequate perfusion at the application site.
- *Protect the sensor from strong ambient light as this may impair measurement accuracy. Choose another application site if the sensor does not provide a signal of sufficient quality within approx. 10 seconds of application.*

Cleaning and Maintenance

Equipment Surface

- Switch ergodesk duo OFF.
- Wipe the device clean with a moist cloth. Do not let liquid enter the device. All cleaning agents and disinfectants commonly used in doctor's offices and hospitals can be used.

CAUTION

• Shock Hazard •

Disconnect the device from the power line and from the PC before cleaning.

• Equipment Damage •

Do not disinfect the device surface with phenol-based disinfectants or peroxide compounds.

Equipment into which liquids have entered must be inspected by a service technician before use.

Cuff Cleaning and Disinfection

- Use a moist cloth to wipe down slightly soiled cuffs.
- Remove substantial contamination by washing the cuff with soap water or a suitable cleaning agent that contains a disinfectant (do not machine-wash).
- Ensure that no liquid penetrates into the cuff bladder or the pressure hose (for this reason, remove the bladder from the cuff before cleaning it).
- After cleaning, rinse the cuff thoroughly with water and let it dry at room temperature for about 15 hours.
- The cuffs can be disinfected with isopropyl alcohol 70%, ethanol 70%, microzid, buraton liquid, Sporicidin or Cidex.
  After disinfection, rinse the cuff thoroughly with tap water and air-dry.

Sensor Cleaning and Disinfection

CAUTION

• Equipment Damage •

Before cleaning an SpO2 sensor, carefully read the user instructions supplied with the sensor. Specific cleaning instructions exist for each sensor type. Observe these sensor-specific instructions when cleaning or disinfecting a sensor.

Maintenance, Technical Inspection of the Measuring System (MTK)

Checks before each use

- Before each use, visually inspect the device for signs of mechanical damage.

- If you detect damage or impaired functions which may result in a hazard to the patient or the operator, the device must be repaired before it can be used again.

Technical Inspections of the Measuring System

ergodesk duo is a measuring system in the sense of the German medical devices operator ordinance (MPBetreibV, §11 / Annex 2). For this reason, the equipment must be subjected to a technical inspection of the measuring system every 2 years, the first such inspection carried out on the date indicated on the calibration seal.

Calibration Mode for BP Measurement System

ergodesk duo offers a calibration mode which is used, for example, to check the pneumatic system for leaks.

- Using a T-adapter, connect a rubber bulb between pressure tubing and cuff.
- Roll up cuff tight.
- Switch off device and switch it on again after a few seconds.
- The display indicates an internal value which must be between 25 and 100.
  If the displayed value is outside this range, ergodesk duo must be returned for repair.
- Press the <ENTER> key:
- The display indicates "0" (current pressure in mmHg).
- Generate a test pressure of 200 mmHg and measure the pressure decrease after waiting at least 30 seconds.
  (Pressure decreases between 3 and 5 mmHg are typical; if the pressure decrease exceeds 6 mmHg, there must be an in admissible leak in the system and ergodesk duo needs to be repaired.)
- You can press the <STOP> or the <ENTER> button to exit the calibration mode.

SpO2 Calibration

The SpO2 measuring unit does not require calibration or maintenance.

Disposal of the Product

At the end of their service life, the product described in this manual and its accessories must be disposed of in compliance with the waste control regulations applicable to this type of product. It must not be disposed of with domestic waste.
If you have questions regarding the disposal of the product or the accessories, please contact ergoline or its representatives.

TECHNICAL SPECIFICATIONS

Blood Pressure Measurement	
Measuring method	oscillometric
Measurement duration	30 to 45 s (depending on patient)
Systolic	60 to 260 mmHg
Diastolic	40 to 220 mmHg
Heart rate	35 to 240 beats/min
Cuff	
Connection	Metal snap lock (Rectus®)
Size	different sizes available
Cuff pressure	300 mmHg max., adjustable
SpO2 Measurement	
SpO2	45 - 100 %
Accuracy	+/- 2% (70% - 100%)
Heart rate	20 to 300 beats/min
Accuracy	+/- 1 BPM <= 100BPM +/- 1 % > 100 BPM
Sensors	
Connection	MiniMed socket
Sensor types	different sensors available
Indicators / Operating Controls	
Display	LCD
Operating controls	membrane keypad
Interfaces	
PC connection	digital interface (USB) GDT driver for Windows
Safety	
MDD product class	II b (BF for SpO2 module)
Miscellaneous	
Dimensions (W x D x H)	19 cm x 17 cm x 20 cm
Operating temperature	+10° to +40°
Rel. humidity	30 - 75 % (non-condensing)
Ambient pressure	700 to 1060 hPa
Power supply	medical-grade AC adapter, 100 to 240 V (50 to 60 Hz)

Electromagnetic Compatibility EN 60601-1-2

Changes or modifications to this system not expressly approved by ergoline could cause EMC issues with this or other equipment.

This system is designed to comply with applicable regulations regarding EMC.

Its compliance with these requirements has been verified. It needs to be installed and put into service according to the EMC information stated as follows.

Warning

• RF INTERFERENCE •

Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected behavior or adverse operation.

Caution

• Equipment Malfunction •

The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions	
ergodesk duo is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that ergodesk duo is used in such an environment.	
Emissions Test	Compliance
RF emissions to CISPR 11	Group 1
RF emissions to CISPR 11	Class B
Harmonic emissions to IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions to IEC 61000-3-3	not applicable
	see 6.8.3.201 a) 3) and Figure 201

Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
ergodesk duo is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that ergodesk duo is used in such an environment.		
Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) to IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air
Electrical fast transient/burst to IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input and output lines
Surges to IEC 61000-4-5	+1kV differential mode +2kV common mode	+1kV differential mode +2kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines to IEC 61000-4-11	<5% UT (> 95% dip in UT) for ½ cycle 40% U (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (> 95% dip in UT) for 5 s	<5% UT (> 95% dip in UT) for ½ cycle 40% U (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (> 95% dip in UT) for 5 s
Power frequency (50/60 Hz) magnetic field to IEC 61000-4-8	3 A/m	3 A/m

NON Life-Sustaining Systems		
Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF to IEC 61000-4-6 Radiated RF to IEC 61000-4-3	3Vrms 150 kHz to 80 MHz 3Vrms 80 MHz to 2.5 GHz	3 V 3 V/m

Recommended separation distances to wireless RF communications equipment			
rated maximum output power of transmitter W	150 kHz to 80 MHz d=P*exp0.5*3.5/V1	80 MHz to 800 MHz d=P*exp0.5*3.5/E1	800 MHz to 2.5 GHz d=P*exp0.5*7/E1
0.01	0.12 m	0.12 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34

ergoline GmbH
Lindenstraße 5
72475 Bitz
Germany

Tel.: +49-(0) 7431 98 94 - 0
Fax: +49-(0) 7431 98 94 - 128
e-mail: info@ergoline.com
http: www.ergoline.com